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APPLICATION FOR UNITED STATES LETTERS PATENT

for

**PERIPHERAL NERVE STIMULATION METHOD**

by

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# PERIPHERAL NERVE STIMULATION METHOD

This application claims benefit of Provisional Appln.  
60/136,690 filed May 29, 1999.

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

This invention relates to a method for subcutaneously electrically stimulating peripheral nerves and in a particular embodiment relates to a method for subcutaneously electrically stimulating one or more occipital peripheral nerve to treat occipital neuralgia.

### 2. Description of Related Art

Peripheral nerves are nerves in the body other than the nerves of the brain or spinal cord. Peripheral nerve injury may result in the development of chronic intractable pain. Some patients prove unresponsive to conservative pain management techniques. Peripheral Nerve Stimulation (PNS) has developed as a successful therapy for pain management when the pain is known to result from a specific nerve. PNS is based in part on the Melzack-Wall gate control theory of pain. Sweet and Wespick first used electrical stimulation of peripheral nerves in the 1960s to mask the sensation of pain with a tingling sensation (paresthesia) caused by the electrical stimulation. Subsequent refinements in the technology, surgical technique and patient selection have led to improved long term results.

PNS is an accepted alternative for those patients who have failed more conservative pain management therapies. Clinical experience has shown that when applied to appropriate patients by trained practitioners, PNS can reduce pain, reduce narcotic intake to manage pain and improve the patient's activity levels and their quality of life. PNS has been recognized to have the following desirable characteristics:

- The surgical procedure is relatively simple.

- PNS is nondestructive. No known permanent surgical or chemical interruption of nerve pathways occurs.
- PNS is reversible. If the patient does not benefit, the device can be turned off or removed. There are no known long-lasting medical or surgical side effects.
- Patients can be tested for response prior to implant of the complete system.

Occipital nerves 2, 4 and 6 (Figure 1) are peripheral nerves that exit the spinal cord at the C2 level of the cervical vertebrae and extend upward generally along the back and back-sides of the head. The lesser occipital nerve 2 extends upward and toward the sides of the head. The greater occipital nerve 4 extends upward toward the top of the head. The third occipital nerve 6 extends from near the neck around the back of the head toward the ear. Because of the location where the occipital nerves leave the spinal cord, the occipital nerves pass from the spinal column through muscle and fascia to the scalp.

Occipital neuralgia is a condition characterized by paroxysms of pain occurring within the distribution of the greater and/or lesser occipital nerves. Occipital neuralgia has been described as a "jabbing" pain in the area of the greater or lesser occipital nerve. The pain may radiate from the back or sides of the head toward the top or front of the head. Patients will vary in their reporting of this pain. It has been characterized in the medical literature as a unilateral or bilateral throbbing pain that frequently radiates to the forehead and to the frontal region (Stechison and Mullin, 1992) or as a lancinating pain extending from the suboccipital region up to the top of the head. The pain is less often described as including or consisting of a dull aching" (Sulfaro and Gobetti, 1995). Occipital neuralgia is often accompanied by diminished sensation and sometimes extreme localized tenderness over the applicable nerve.



1 occipital nerve trunk and subsequent electrical stimulation of the occipital nerve trunk. This  
2 stimulation produces paresthesia and pain relief covering the regions of occipital nerve pain.

3 It is therefore an object of the invention to provide a method for subcutaneously  
4 electrically stimulating nerves causing pain to create paresthesia.

5 It is another object of the invention to provide a method for percutaneously placing  
6 leads subcutaneously to create paresthesia.

7 These and other object of the invention will be clear from the following detailed  
8 description of the invention.

#### 9 BRIEF DESCRIPTION OF THE DRAWINGS

10 Figure 1 is a schematic view of the occipital nerves.

11 Figure 2 is a schematic view of the hardware used to practice the invention of the  
12 present invention.

13 Figure 3 is a perspective view of a screener device and a screening lead.

14 Figure 4 is a top view of a permanent lead.

15 Figure 5 is a perspective view of an implantable pulse generator (IPG).

16 Figure 6 is a perspective view of an RF system receiver and an RF system transmitter.

17 Figure 7 is a top view of an introducer needle curved to facilitate placement of the  
18 permanent lead to treat occipital neuralgia.

19 Figure 8 is a schematic view of the entry site used to implant a screening lead or a  
20 permanent lead for treating occipital neuralgia.

21 Figure 9 is a schematic view of the placement of the introducer needle prior to placing  
22 the screening lead.

1 Figure 10 is a schematic view of the placement of the introducer needle with the  
2 screening lead being inserted into the introducer needle.

3 Figure 11 is a schematic view of dual leads placed to treat bi-lateral pain.

4 Figure 12 is a perspective view of a patient prior to being implanted with a permanent  
5 lead.

6 Figure 13 is a schematic view of the placement of the introducer needle prior to placing  
7 the permanent lead.

8 Figure 14 is a schematic view of the placement of the introducer needle with the  
9 permanent lead being inserted into the introducer needle.

10 Figure 15 is a schematic view of the location of the subcutaneous pocket for housing  
11 the loop of the permanent lead and the lead anchor.

12 Figure 16 is a perspective view of a human torso and arm showing the location of the  
13 leads for two embodiments of the invention.

14 Figure 17 is a perspective view of a human torso and arm showing the exit sites of the  
15 leads and preferred location for an IPG for the method of Figure 16.

16 Figure 18 is a perspective view of a human leg showing the location of a lead and IPG  
17 for an embodiment of the invention.

18 Figure 19 is a perspective view of a human leg showing the location of a lead and IPG  
19 for another embodiment of the invention.

## 20 DETAILED DESCRIPTION OF THE INVENTION

21 The present invention comprises a method of stimulating peripheral nerves. The  
22 method is preferentially accomplished in two stages: a test implantation and screening stage  
23 and a permanent implantation of a lead and electrical stimulation system stage. The invention

1 contemplates using, as shown in Figure 2, a screening lead 10 (shown in detail in Figure 3), a  
2 screener device 12 (also shown in detail in Figure 3), a permanent lead 14 (shown in detail in  
3 Figure 4) and either an implanted pulse generator (IPG) 16 (shown in detail in Figure 5) or an  
4 implanted RF system receiver 18 and its corresponding RF system transmitter 20 (shown in  
5 detail in Figure 6).

6 The screening lead 10 and permanent lead 14 are preferably percutaneous leads chosen  
7 from the Pisces-Quad® family of quadripolar leads. Screener device 12 is preferably a Model  
8 3625 Screener or a Model 3628 DualScreen® Screener. IPG 16 is preferably an Itrel® IPG.  
9 RF system receiver 18 and RF system transmitter 20 are both preferably part of an RF  
10 stimulation system such as the X-trell® or Matrix® RF Stimulation Systems. Screening lead  
11 10, permanent lead 14, screener device 12, IPG 16, RF system receiver 18 and RF transmitter  
12 20 are all available from Medtronic, Inc. of Minneapolis, Minnesota.

13 The method for treating pain due to peripheral nerves involves subcutaneous placement  
14 of a permanent lead 14 transversely across the peripheral nerve that is causing the pain. This  
15 peripheral nerve is subsequently electrically stimulated to cause paresthesia of the painful area.  
16 The method also preferably involves placement of a screening lead 10 and subsequent test  
17 electrical stimulation prior to placing the permanent lead 14. Although the method preferably  
18 involves placing both a screening lead 10 and then a permanent lead 14, the method also  
19 includes implanting just the permanent lead 14 as will be described in detail hereafter. For  
20 illustration purposes, the method for treating pain due to peripheral nerves will be described  
21 with reference to treating occipital neuralgia by electrically stimulating the occipital nerves.

22 One key to the technical success of this invention is the accurate placement of the  
23 permanent lead 14. Because of the importance of accurate placement of the permanent lead

1 14, accurate placement of permanent lead 14 is facilitated by the placement of the screening  
2 lead 10 and the subsequent test electrical stimulation. The steps in the invention to  
3 percutaneously place a screening lead 10 to treat occipital neuralgia will now be described in  
4 detail. These steps are given as the preferred method of implementing the invention for most  
5 patients. It is recognized, however, that the skilled physician will adapt the method described  
6 herein using his or her professional skill and judgment to the particular circumstances of a  
7 particular patient. Further, although the method of treating pain described in detail herein is  
8 specifically directed to treating occipital neuralgia, unless otherwise specifically directed, any  
9 reference to the occipital nerve or occipital neuralgia refers as well to any peripheral nerve or  
10 neuralgias corresponding to a peripheral nerve, respectively.

11 The first step of the test implantation and screening stage is the implantation of a  
12 screening lead 10. The method involves subcutaneous placement of a screening lead 10 in the  
13 fascia 34 above (superior to) the occipital nerve causing pain and proximal to the level of  
14 detected pain. The first step in locating the area to implant the screening lead 10 is to palpate  
15 the area of pain to identify the specific nerve that is causing the pain. If it is confirmed that an  
16 occipital nerve is causing the pain and the specific occipital nerve has been identified, an  
17 introducer needle 22 is used to place the screening lead 10.

18 The preferred embodiment for the introducer needle 22 is a Touhy needle. As shown  
19 in Figure 7, the introducer needle 22 has a terminal end 24 that has a beveled edge 26 and a  
20 proximal end 28 that includes a hub 30. Beveled edge 26 is a sharp edge that allows the  
21 terminal end 24 to be pushed through tissue. Hub 30 allows the physician to manipulate the  
22 introducer needle 22. Hub 30 also has a notch 32 that is aligned with the beveled edge 26 to  
23 indicate the orientation of beveled edge 26 to the hub 30 by tactile sensation.



1 The introducer needle 22 is then subcutaneously placed in the fascia 34 above (superior  
2 to) the nerve 36 that is causing the pain. In the case of treating occipital neuralgia, the  
3 introducer needle 22 is placed in the fascia 34 above (superior to) the occipital nerve that is  
4 causing the pain. Fascia 34 is a sheet of fibrous tissue that envelops the body under the skin  
5 and also encloses the muscles. In the described method, the introducer needle 22 will be  
6 introduced into the fascia 34 so that the introducer needle will be between the patient's skin  
7 and muscle. The nerve causing the pain will be located within or under the musculature. In the  
8 case of treating occipital neuralgia, the introducer needle 22 will be introduced into the fascia  
9 34 so that the introducer needle will be between the patient's skin and the occipital nerve.

10 The introducer needle 22 is preferably introduced through a small stab wound "A" at  
11 the needle entry site (Figure 8). Rapid needle insertion is preferably used. This technique  
12 usually obviates the need for even a short acting general anesthetic.

13 The introducer needle 22 is moved through the fascia 34 to a position over the occipital  
14 nerve that is causing the pain (Figure 9). When the introducer needle 22 is in position above  
15 the occipital nerve, the screening lead 10 is passed through the introducer needle 22 (Figure  
16 10) until the screening lead 10 is also in position above the occipital nerve causing the pain.  
17 Then, the introducer needle 22 is removed leaving the screening lead 10 in place above the  
18 occipital nerve.

19 Single or dual quadripolar as well as single or dual octapolar screening leads 10 may be  
20 used depending on whether the pain is unilateral (on one side of the body only) or bilateral (on  
21 both sides of the body). Where the pain is bilateral and two screening leads 10 are used (Figure  
22 11), each screening lead 10 will be placed as described above.

1           Following placement of the screening lead 10 by the introducer needle 22, the  
2 screening lead 10 is connected to the screening device 12, as is well understood in the art.  
3 With the screening lead 10 in place as described above and the screening lead 10 connected to  
4 the screening device 12, the patient is electrically stimulated by the screening lead 10 and  
5 screener device 12 to evaluate the screening lead 10 position and to develop optimal  
6 stimulation parameters. Stimulation is applied using the screener device 12 to select various  
7 electrode combinations, enabling the patient to report stimulation location, intensity and overall  
8 sensation. This allows the physician to test the stimulation and determine optimum stimulation  
9 parameters prior to permanently implanting the permanent lead 14 and the source of electrical  
10 stimulation pulses, either the IPG 16 or the RF system receiver 18. The effect of this  
11 stimulation is determined and the parameters of stimulation adjusted for optimal pain relief. It  
12 is preferred that the patient be awake and alert so that the patient will provide verbal feedback  
13 regarding paresthesia coverage of the painful area to assist in determining the optimum  
14 stimulation parameter settings.

15           The following have been found to be typical ranges for stimulation parameters for  
16 screening by the screener device 12 and the screening lead 10 to optimize paresthesia levels for  
17 pain coverage. These parameters can vary from patient to patient and may be outside the  
18 ranges given here. Never-the-less, these representative values are given for the purpose of  
19 illustrating the invention and not for the purpose of limiting the invention. Values for these  
20 parameters may be higher or lower than the values shown.

21                           Amplitude:           0.5 - 4.0 volts  
22                           Pulse Width:        90 - 200  $\mu$ sec  
23                           Rate:                50 - 400 Hz

1 If the patient reports muscle contractions (grabbing sensation) or burning, this usually  
2 indicates that the screening lead 10 is located too deep (anterior) in the subcutaneous tissue. It  
3 may also indicate that the screening lead 10 is not positioned correctly above (superior to) the  
4 nerve. It may be necessary to remove and reposition the screening lead 10. If adjustment of  
5 screening lead 10 is necessary, the screener device 12 is removed from the screening lead 10.  
6 Then, the position of the screening lead 10 is adjusted and stimulation is tested again for  
7 optimal pain relief. Adjusting the position of the screening lead 10 may mean removing the  
8 screening lead 10 and re-implanting the screening lead 10 according to the technique described  
9 above.

10 After good paresthesia coverage is obtained by manipulating the parameters of  
11 stimulation applied through screening lead 10, percutaneous testing wires can be externalized  
12 for the test stimulation period as is well understood in the art. This period is used to evaluate  
13 the patient's response to stimulation before complete implantation of all system components.

14 Alternately, once satisfactory paresthesia is confirmed, the screener device 12 may be  
15 removed from the screening lead 10 and a source of electrical stimulation pulses such as the  
16 IPG 16 or RF system receiver 18 is immediately implanted and attached to the screening lead  
17 10. Hence, screening lead 10 in this embodiment becomes permanent lead 14. However, it is  
18 preferred that the patient use the implanted screening lead 10 and screener system 12 for  
19 several days prior to implanting a permanent stimulation system.

20 Once the screening lead 10 has been appropriately positioned and tested, if satisfactory  
21 results are obtained, the method should proceed to the "permanent implantation of a lead and  
22 electrical stimulation system" stage. The steps in the invention to permanently implant a  
23 stimulation system will now be described in detail in connection with the treatment of occipital

1 neuralgia. As mentioned above, it is possible to implant a source of electrical stimulation pulses  
2 such as the IPG 16 or RF system receiver 18 and attached it directly to the screening lead 10 so  
3 that screening lead 10 becomes the permanent lead 14. However, the preferred embodiment of  
4 the invention contemplates removing the screening lead 10 and replacing it with a permanent  
5 lead 14.

6 After it has been determined that the patient is receptive to pain relief from electrically  
7 stimulating the peripheral nerve causing the pain and the paresthesia associated with the  
8 electrical stimulation has been maximized, the screener device 12 is disconnected from the  
9 stimulation lead 10 and the screening lead 10 is removed. The patient is then prepared for  
10 placement of the permanent lead 14 and the implanted pulse generator (IPG) 16 or implanted  
11 RF system receiver 18. The purpose of the "permanent implantation of a lead and electrical  
12 stimulation system" stage is to internalize (that is, implant) the permanent lead 14 and either the  
13 IPG 16 or the RF system receiver 18. Therefore, this stage includes implanting the permanent  
14 lead 14, neurostimulator (either IPG 16 or RF system receiver 18) and any extension  
15 sometimes used to connect permanent lead 14 and either IPG 16 or RF system receiver 18 as is  
16 well understood in the art.

17 As stated above, one key to the technical success of this invention is the accurate  
18 placement of the permanent lead 14. It is therefore crucial to the success of the invention to  
19 have a lead placement for the permanent lead 14 that results in paresthesia that covers the  
20 patient's painful area. Therefore, lead placement is preferably determined using patient  
21 feedback during intraoperative testing of the efficacy of the permanent lead 14 placement and  
22 the stimulation parameters. Performing implantation of the permanent lead 14 under local  
23 anesthetic allows for this feedback.

1 A local anesthetic is preferably used in the area of the introducer needle 22 entry site to  
2 ensure the patient is alert and able to respond during the procedure. To help the patient relax,  
3 sedatives are also preferably administered intravenously. Prophylactic antibiotics can also be  
4 administered intravenously for protection from postoperative infection. As a result, the patient  
5 is preferably awake and alert during the placement of the permanent lead 14 and the subsequent  
6 test stimulation.

7 Where treating occipital neuralgia, the patient is preferably placed in a lateral position,  
8 or in a prone position with the head to the side, on a radiolucent table (Figure 12). The patient  
9 is prepared and draped according to standard surgical procedure. Fluoroscopy is used to  
10 identify the location of the C1 vertebra. The location and midline of the C1 vertebra is marked  
11 on the patient's skin with a sterile marker.

12 A Touhy needle is preferably used as an introducer needle 22 to introduce permanent  
13 lead 14. The introducer needle 22 includes a stylet 42. The introducer needle 22 is manually  
14 gently curved by the physician to conform to the contour of the patient's body above the  
15 peripheral nerve to facilitate placement of the permanent lead 14. Where the peripheral nerve is  
16 the occipital nerve, the introducer needle 22 is manually gently curved by the physician to  
17 conform to the contour of the patient's neck (Figure 7) to facilitate placement of the permanent  
18 lead 14.

19 A small stab wound "A" is made at the needle entry site (Figure 8) at the C1 level.  
20 Using local anesthesia, a 2 cm. vertical skin incision is made in the patient's neck lateral to the  
21 midline of the spine at the level of C1. The introducer needle 22 is introduced into the  
22 subcutaneous tissue, superficial to the fascia 34 and muscle layer but below the skin, without

1 further dissection across the trunk of the occipital nerves. These nerves are located within the  
2 cervical musculature and overlying fascia 34.

3 The physician then advances the introducer needle 22 transversely from the lateral  
4 incision point to and across the midline of the spine under fluoroscopic observation to the  
5 appropriate location above the trunk of the occipital nerve (Figure 13). The beveled edge 26 of  
6 the introducer needle 22 should face toward the front of the body (anterior). The orientation of  
7 the beveled edge 26 can be verified by referring to the notch 32 on the needle hub 30 of the  
8 introducer needle 22.

9 The curve of the introducer needle 22 may be checked, if desired, by the physician by  
10 removing and re-inserting the needle stylet 42. A useful, curved introducer needle 22 is  
11 ensured if it is easy to remove and reinsert the stylet 42 within the introducer needle 22. If  
12 desired, an additional check can be made by removing the stylet 42, then carefully inserting the  
13 permanent lead 14 through the introducer needle 22 to just beyond the beveled edge 26 of the  
14 introducer needle 22. If the curvature of the introducer needle 22 is correct, the permanent  
15 lead 14 should pass easily to just beyond the beveled edge 26 of the introducer needle 22. The  
16 permanent lead 14 is then removed and the stylet 42 re-inserted into the introducer needle 22.

17 Once the desired position has been reached, the stylet 42 is removed from the  
18 introducer needle 22. The permanent lead 14 is slowly inserted through the introducer needle  
19 22 until the distal tip 36 of the permanent lead 14 just exits the introducer needle 22 (Figure  
20 14). Then, the introducer needle 22 is carefully removed over the permanent lead 14. The  
21 permanent lead 14's placement is verified with fluoroscopy. Alternately, the introducer needle  
22 22 can be partially removed. This allows the electrode contacts on the permanent lead 14 to be  
23 exposed while facilitating introducer needle 22 reinsertion if repositioning of the permanent

1 lead 14 is needed. Fluoroscopy is used to ensure that all electrodes of the permanent lead 14  
2 are exposed. If necessary, the introducer needle 22 may be adjusted to move the permanent  
3 lead 14 to a location where the permanent lead 14 will optimally stimulate the targeted occipital  
4 nerve(s).

5 If more than one permanent lead 14 is to be implanted, for example, on each side of the  
6 midline to treat bilateral pain, the procedure described above is repeated for each such  
7 permanent lead 14.

8 Following placement of the permanent lead 14 by the introducer needle 22, the  
9 permanent lead 14 is again connected to the screening device 12, as is well understood in the  
10 art. This allows the physician to test the stimulation and confirm that paresthesia is obtained  
11 with the placement of the permanent lead 14 prior to permanently implanting the IPG 16 or the  
12 RF system receiver 18. Since the patient is preferably awake and alert, the patient will provide  
13 verbal feedback regarding paresthesia coverage of the painful area to assess the placement of  
14 the permanent lead 14.

15 If the patient reports muscle contractions (grabbing sensation) or burning, this usually  
16 indicates that the electrodes on the permanent lead 14 are too deep (anterior) in the  
17 subcutaneous tissue. It may also indicate that the electrodes are significantly above or below  
18 the C1 landmark. It may be necessary to remove and reposition the permanent lead 14. If  
19 adjustment of permanent lead 14 is necessary, the screener device 12 is removed from the  
20 permanent lead 14. Then, the position of the permanent lead 14 is adjusted and stimulation is  
21 tested again.

22 After good paresthesia coverage is obtained, the screener device 12 is removed from  
23 the permanent lead 14. It is now possible to implant the source of electrical stimulation pulses

1 such as the IPG 16 or RF system receiver 18 and any extension sometimes used to connect  
2 permanent lead 14 and either IPG 16 or RF system receiver 18 as is well understood in the art.  
3 Internalization of the neurostimulation system for occipital nerve stimulation preferably follows  
4 the protocol used for other Peripheral Nerve Stimulation (PNS) indications as is well  
5 understood in the art. Basically, the procedure involves creating a subcutaneous pocket 24 in  
6 tissue (Figure 15), anchoring the permanent lead 14, implanting the IPG 16 or RF system 18,  
7 tunneling the permanent lead 14 and connecting the permanent lead 14 to the IPG 16 or RF  
8 system 18 as is well understood in the art.

9 The following have been found to be typical ranges for stimulation parameters applied  
10 to the permanent lead 14 to obtain optimum paresthesia levels for pain coverage to treat  
11 occipital neuralgia. These values can vary from patient to patient and may be outside the ranges  
12 given here. Never-the-less, these representative values are given for the purpose of illustrating  
13 the invention and not for the purpose of limiting the invention. Again, values for these  
14 parameters may be higher or lower than the values shown.

15 Amplitude: 0.5 - 4.0 volts  
16 Pulse Width: 90 - 200  $\mu$ sec  
17 Rate: 50 - 400 Hz

18 These steps are given as the preferred method of implementing the invention for most  
19 patients. It is recognized, however, that the skilled physician will adapt the method described  
20 herein using his or her professional skill and judgment to the particular circumstances of a  
21 particular patient.

22 A specific example of percutaneous nerve stimulation has been given for treating  
23 occipital neuralgia. Although the method of treating occipital neuralgia has been described in



1 detail, the steps described can be adapted to treating other peripheral nerve applications as  
2 medical judgment and necessity require. Examples of other applications for the described  
3 subcutaneous PNS technique include peripheral nerves in the head and neck, trunk and limbs.  
4 Examples of neuralgias in the head and neck that can be treated by stimulating peripheral  
5 nerves include, but are not limited to, post herpetic neuralgia, chronic deafferentation pain,  
6 chronic peripheral nerve pain, post craniotomy pain and incisional pain. For post herpetic  
7 neuralgia, the permanent lead 14 should preferably be placed in the vicinity of the supraorbital  
8 nerve in the forehead area. For chronic deafferentation pain, the permanent lead 14 should  
9 preferably be placed subcutaneously in the vicinity of the deafferentation pain. For chronic  
10 peripheral nerve pain, the permanent lead 14 should preferably be placed proximal to any  
11 peripheral nerve throughout the body. For chronic post craniotomy pain, the permanent lead  
12 14 should preferably be placed in the region of the craniotomy incision.

13 Examples of neuralgias in the trunk that can be treated by stimulating peripheral nerves  
14 include, but are not limited to, clunial nerve pain, post herniorrhaphy pain, localized low back or  
15 other spine pain and incisional neuroma pain. For clunial nerve pain, the permanent lead 14  
16 should preferably be placed over the clunial nerve in the buttock area. For post herniorrhaphy  
17 pain, the permanent lead 14 should preferably be placed subcutaneously in the region of the  
18 iliolumbar nerve. For localized low back or other spine pain, the permanent lead 14 should  
19 preferably be placed in the vicinity of the localized area of pain. For incisional neuroma pain,  
20 the permanent lead 14 should preferably be subcutaneously placed in the region of the  
21 incisional neuroma.

22 Examples of neuralgias in the limbs that can be treated by stimulating peripheral nerves  
23 include, but are not limited to, stump neuroma pain, incisional scar pain, deafferentation pain and

1 chronic peripheral nerve pain as for example with the median nerve or ulnar nerve. For stump  
2 neuroma pain, the permanent lead 14 should preferably be subcutaneously placed in the region  
3 of the neuroma. For incisional scar pain, the permanent lead 14 should preferably be  
4 subcutaneously placed in the region of the incision. For chronic peripheral nerve pain of the  
5 medial nerve or ulnar nerve, the permanent lead 14 should preferably be placed over the medial  
6 nerve 38 or ulnar nerve 40, respectively, as shown in Figure 16. Here, the technique described  
7 above is applied to the placement of screening lead 10 and permanent lead 14 with the leads  
8 10, 14 located above (superior to) the desired peripheral nerve through medial nerve incision  
9 site 42 and ulnar nerve incision site 44, respectively. Once the permanent lead 14 is in place,  
10 the IPG 16 or RF system receiver 18 is implanted as is well understood in the art (Figure 17)  
11 and connected to the permanent lead 14.

12 Figures 18 shows the placement of a permanent lead 14 next to the sciatic nerve 46 in  
13 the leg. Permanent lead 14 is implanted as described above through the sciatic nerve incision  
14 site 48. Placement of permanent lead 14 and the subsequent electrical stimulation of the sciatic  
15 nerve 46 could treat neuromas or chronic pain emanating from this peripheral nerve.

16 Further, Figure 19 shows the placement of a permanent lead 14 next to a peripheral  
17 nerve 48 in the ankle, foot or other localized area of pain. Permanent lead 14 is implanted as  
18 described above through a peripheral nerve incision site 50. Placement of permanent lead 14  
19 and the subsequent electrical stimulation of the affected peripheral nerve 44 could also treat  
20 neuromas in or around this peripheral nerve and also chronic pain arising from this nerve.

21 The examples of the method of the invention shown in Figures 16 – 19 have been given  
22 to illustrate examples of peripheral nerves to which the present method could apply. The  
23 application of the present invention to other peripheral nerves with their corresponding

maladies and neuromas will occur to those skilled in the art. Conversely, once neurological  
maladies or neuromas and their corresponding peripheral nerves have been identified, as will  
also occur to those skilled in the art, the present invention may be used to treat such maladies  
or neuromas. It is clear that those skilled in the art will be able to practice the invention  
described above as applied to any peripheral nerve or to treat any particular neuroma by  
applying the disclosed method to its corresponding peripheral nerve.

The description contained herein is intended to be illustrative and not exhaustive.  
Many variations and alternatives will occur to one of ordinary skill in this art. All these  
alternatives and variations are intended to be included within the scope of the attached claims.  
Those familiar with the art may recognize other equivalents to the specific embodiments  
described herein which equivalents are also intended to be encompassed by the claims attached  
hereto.